

PATENT COOPERATION TREATY
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

REC'D 14 FEB 2000

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 721938	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU 99/00165	International filing date (day/month/year) 16 March 1999	Priority Date (day/month/year) 16 March 1998
International Patent Classification (IPC) or national classification and IPC Int. Cl.⁶ A01K 67/00, C12N 15/06, A61K 35/54		
Applicant BresaGen Limited <i>et al.</i>		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 5 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s).
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input checked="" type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application

Date of submission of the demand 12 October 1999	Date of completion of the report 28 January 2000
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer T. SUMMERS Telephone No. (02) 6283 2291

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , filed with the letter of .
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , filed with the letter of .
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , filed with the letter of .
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , filed with the letter of .

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	YES
	Claims 1-18	NO
Inventive step (IS)	Claims	YES
	Claims 1-18	NO
Industrial applicability (IA)	Claims 1-18	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

D1 - Nagashima *et al.*
D2 - Prather *et al.* (1989)
D3 - WO97/07668
D4 - WO97/07669
D5 - WO98/37183
D6 - WO99/01164
D7 - WO99/05266

NOVELTY(N) & INVENTIVE STEP(IS)

D3 and D4 disclose the production of nuclear transferred embryonic cells by the transfer of a diploid donor cell into an enucleated oocyte recipient arrested in metaphase II stage of development (D3 page 12 paragraph 2; D4 page 11 line 22-page 12 line 28). D3 further discloses that the donor cell must be in the G1 or G0 phase of the cell cycle (page 7 line 15-page 8 line 11). Similarly, D4 discloses that the donor cell must be in the G0 phase (page 8). Both documents also disclose the production of transgenic animals from the nuclear transferred embryos. Although these documents exemplify the production of bovine and ovine nuclear transferred embryos, the disclosed processes are clearly suitable for the production of embryos of other ungulates including pigs (D3 claim 3, D4 claim 3). Consequently claims 1-16 are not novel and do not involve an inventive step.

D1-D4 disclose methods for producing nuclear transferred porcine embryos and/or transgenic animals. Consequently claims 17-18 are not novel and do not involve an inventive step.

D5-D7 were published after the earliest priority date. See the indication contained in Box VI "Certain documents cited".

VI. Certain documents cited**1. Certain published documents (Rule 70.10)**

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
P,X WO98/37183A	27 August 1998	20 February 1998	20 February 1997
P,X WO99/01164A	14 January 1999	1 July 1998	3 July 1997
P,X WO99/05266A	4 February 1999	24 July 1998	26 July 1997

WO98/37183 and WO99/01164 disclose all the features of claims 1-18.

In particular donor cells are synchronised in the G0 or G1 phase of the cell cycle (see page 19 lines 24-29 of WO98/37183 and page 38 lines 15-26 of WO99/01164).

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 17 and 18 are not supported by the description because they are not limited to a cloned pig when produced by a process comprising the inventive nuclear transfer process (ie a process as defined in claim 1).